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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,524	12/29/2003	Richard E. Parizek	I 1995.184 US D1	8568

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PATENT DEPARTMENT
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EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
07/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,524	PARIZEK ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 10, 2007 has been entered.

Amendment Entry

2. The amendment filed February 24, 2005 has been entered. Claims 2 and 23 have been amended. Claims 1-45 have been cancelled. Claims 46-48 have been amended. Claims 46-48 are under consideration in this office action.

Withdrawal of Rejection

3. The rejection of claims 1-3,15, 17-19 and 40 under 35 U.S.C. 102(b) as being anticipated by Roberts (WO 94/22476), has been withdrawn in view of applicants amendments and arguments.

Response to Arguments

4. Applicant's arguments with respect to claims 1-3,15, 17-19 and 40 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Objection

Claim Objections

5. Claims 46-48 are objected to because of the following informalities: The claims do not include the active step of injecting the vaccine into the cattle. It is suggested that the claim language recite "...injecting 3ml or less of a multicomponenet vaccine **into said** cattle...."

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 46-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The term "significant injection site lesion formation" in claims 46-48 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear how to define significant lesion formation. The metes of bounds of what is significant are not defined. Therefore appropriate clarification is required to overcome the rejection.

b) Claim 48 recites the limitation "...the protective antigen component from at least one non-clostridial organism which is *M. bovis...* " in the claim. There is

insufficient antecedent basis for this limitation in the claim. It is suggested that the claim language recite "...**a** protective antigen component from at least one non-clostridial organism which is *M. bovis*... ".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts (WO 94/22476, published October 13, 1994) in view of Lund (3,920,811 published November 18, 1975).

Claim 46 is drawn to a method of immunizing cattle without significant injection site lesion formation comprising amount of injecting 3 ml or less of a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component from six clostridial organisms, a protective antigen component from at least one non-clostridial organism which is *Moraxella bovis* (*M.bovis*) and an encapsulating polymer adjuvant whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection without significant permanent injection site lesion formation.

Claim 47 is drawn to a method of immunizing cattle without significant injection site lesion formation comprising amount of injecting 3 ml or less of a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component from seven clostridial organisms, a protective antigen component from at least one non-clostridial organism which is *M. bovis* and an encapsulating polymer adjuvant whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection without significant permanent injection site lesion formation.

Claim 48 is drawn to a method of immunizing without significant injection site lesion formation comprising amount of injecting 3 ml or less of a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component *Cl. chauvoei, Cl. septicum, Cl novyi, Cl. perfringens type Cl, CL perfringens type D, CL. sordellii Cl. tetani* and *Cl. haemolyticum*, the protective antigen component from at least one non-clostridial organism which is *M. bovis* and an encapsulating polymer adjuvant whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection without significant permanent injection site lesion formation.

Roberts teaches a multicomponent clostridial vaccine comprising *Clostridium chauvoei*, *Clostridium septicum, Clostridium novyi, Clostridium sordellii, Clostridium perfringens,* Type C and Type D and *Clostridium haemolyticum,* and an adjuvant (page 3 lines 1-5). Roberts teaches that non-clostridial antigens such as *Moraxella bovis,* are added to the multicomponent vaccines in order to afford protection against a wide spectrum of diseases (page 5 lines 10-15). Roberts teaches the bacterins and toxoids

are administered in vaccine compositions including readily dispersible soluble adjuvants thereby avoiding chronic irritation at the injection site (page 6, lines 13-15). Roberts teaches that the dispersible, soluble adjuvants exhibit low tissue reactivity (page 4, lines 26-28). Roberts teaches immunizing cattle or bovine, by injecting between 1 to 5ml wherein the injection amount is as low as 0.5ml (page 8 lines 24-34).

Roberts teaches that the vaccines are administered without harmful side effects and chronic inflammatory responses that produce granulomas and abscesses (page 4, lines30-33). Roberts teaches that clostridial vaccines require adjuvants in order to increase potency and enhance stability (page 1, lines 32-35). Roberts discloses that other potent adjuvants have been used with clostridial vaccines, including CARBOPOL ™ polymers (page 2, lines 1-5). However Roberts does not specifically recite an encapsulating polymer adjuvant whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection without significant permanent injection site lesion formation.

Lund teaches an adjuvant polymer, such as CARBOPOL ™, is retained at the site for prolonged slow release that acts by adsorbing the active agent onto the polymer (col.1-2, lines 67-5). Lund teaches the inclusion of active agents such as *Cl. Perfringens* Types B, C and D, *Cl. tetani*, *Clostridium chauvoei*, *Clostridium septicum, Clostridium haemolyticum, Clostridium novyi,* and *Clostridium sordellii* whose effects are prolonged or enhanced by their inclusion with the adjuvant polymers (col.5, lines 24-38). Examples 17-19 teach injecting CARBOPOL ™ and *Clostridial* bacterins without significantly lowering the potency of the *Clostridium* bacterins.

It is noted that the instant specification teaches that adjuvants polymers, function by encapsulating antigens and releasing them slowly (page 15, lines 13-18). The adjuvants are polymers, including block copolymers wherein a specific example of the preferred adjuvant is CARBOPOL ™ (page 15, lines 23-28). Therefore, inherently the CARBOPOL ™ is an encapsulating polymer adjuvant that releases antigens slowly at the site of injection without significant permanent injection site lesion formation.

Therefore it would have been prima facie obvious at the time of applicants' invention to apply the encapsulating polymer adjuvant of Lund's to Roberts method of immunizing cattle in order to avoid irritation and significant lesion formation at the injection site. One of ordinary skill in the art would have a reasonable expectation of success by exchanging the readily dispersible soluble adjuvants of Roberts for the adjuvant polymer of Lund because Roberts teaches that clostridial vaccines require adjuvants in order to increase potency and enhance stability of the bacterins and that clostridial vaccines are known to include CARBOPOL ™ polymers. Furthermore, no more than routine skill would have been required to exchange the adjuvant of Roberts for the commercially available and functionally equivalent encapsulating polymer adjuvant of Lund since Lund teaches that adjuvant polymers are retained at the injection site for prolonged slow release of antigens. Finally it would have been prima facie obvious to combine the invention of Roberts and Lund to advantageously achieve low tissue reactivity within the cattle and avoid chronic inflammatory responses, granulomas and abscesses.

Conclusion

8. No claims allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
June 10, 2007

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER